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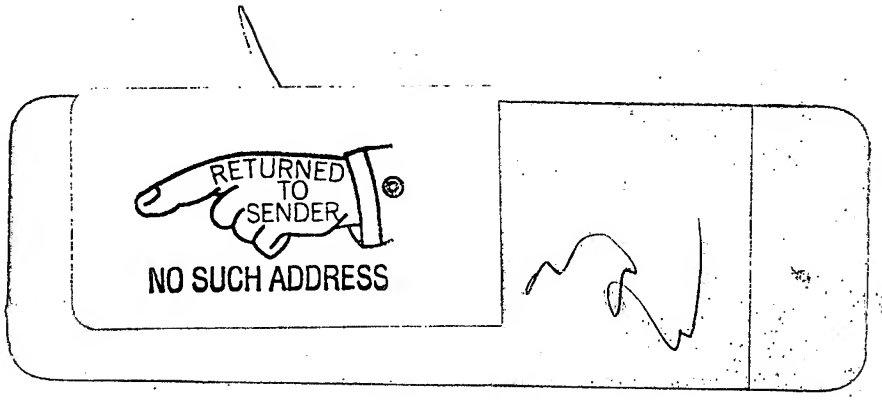

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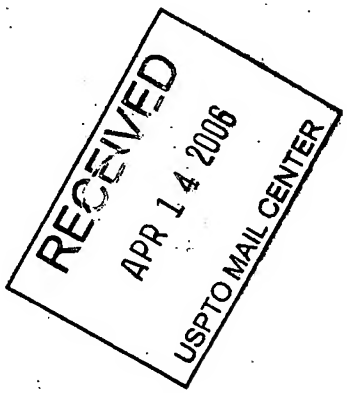

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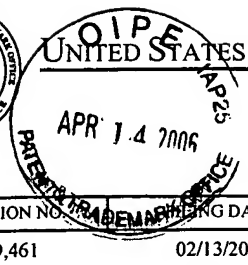

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/779,461	02/13/2004	Phillip A. Morton	00980/1	9486

7590 03/03/2006

Pharmacia Corporation
Global Patent Department
Mail Zone MC5
P. O. Box 1027
St. Louis, MO 63141

EXAMINER	
TUNGATURTHI, PARITHOSH K	
ART UNIT	**PAPER NUMBER**
1643	

DATE MAILED: 03/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/779,461	MORTON ET AL.	
	Examiner	Art Unit	
	Parithosh K. Tungaturthi	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-40* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper-No(s)/Mail-Date-____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 23 in part, 1-30, drawn to an antibody or antigen binding portion thereof that specifically bind to c-MET, classified in class 530, subclass 387.1+, for example.

Please note that claims "1 and 23" and "13" consist of a list of antibodies and the amino acid sequences that possibly encode the antibodies of claim 1 and / or claim 23, respectively. The applicant is requested to select one antibody and one amino acid sequence encoding the corresponding the one selected antibody. Please be advised that this is **NOT A SPECIES ELECTION**, because all the antibodies and the amino acid sequences as listed represent separate and distinct inventions.

II. Claim 23 in part drawn to an antibody or antigen binding portion thereof that cross-competes for binding to human c-MET antibody with the c-MET antibody selected claims 1 or 13, classified in class 530, subclass 387.1+, for example.

Please note that claims "1 and 23" and "13" consist of a list of antibodies and the amino acid sequences that possibly encode the antibodies of claim 1 and / or claim 23, respectively. The applicant is requested to select one antibody and one amino acid sequence encoding the corresponding the one selected antibody. Please be advised

that this is **NOT A SPECIES ELECTION**, because all the antibodies and the amino acid sequences as listed represent separate and distinct inventions.

III. Claim 31, drawn to an isolated cell line that produces an antibody, classified in class 435, subclass 325+, for example.

IV. Claim 32, drawn to a method of diagnosing the presence or location of an HGF expressing tumor in a subject in need thereof, classified in class 424, subclass 9.1, for example.

V. Claim 32, drawn to a method of treating cancer in a human, comprising the step of administering to said human an effective amount of said antibody, classified in class 514, subclass 2, for example.

VI. Claims 34-37, drawn to an isolated nucleic acid that comprises a nucleic acid sequence that encodes a heavy chain or antigen-binding thereof or a light chain or antigen-binding thereof, classified in class 536, subclass 23.1, for example.

Please note that claim 35 consists of a list of nucleic acid sequences that possibly encode the antibodies of claim 1. The applicant is requested to select one nucleic acid sequence from the list provided. Please be advised that this is **NOT A SPECIES ELECTION**, because all the nucleic acid sequences as listed represent separate and distinct inventions.

VII. Claim 38, drawn to an antibody or an antigen biding portion thereof, wherein said antibody or antigen biding portion is a partial agonist against C-MET, classified in class 530, subclass 387.1+, for example.

VIII. Claim 39, drawn to an antibody or an antigen biding portion thereof, wherein said antibody or antigen biding portion blocks HGF driven proliferation, classified in class 530, subclass 387.1+, for example.

IX. Claim 40, drawn to an antibody or an antigen biding portion thereof, wherein said antibody or antigen biding portion blocks HGF binding to human c-MET, classified in class 530, subclass 387.1+, for example.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups I, II, III and VI-IX represent separate and distinct products which are made by materially different methods, and are used in materially different methods which have different modes of operation, different functions and different effects. The antibodies of Group I, II and VIII-IX, the hybridoma product of Group III, and the DNA molecule of Group VI are all structurally and chemically different from each other. The polynucleotide is made by nucleic acid synthesis, the antibody is raised by immunization, and the hybridoma product can be used to produce any antibody other than the claimed antibodies. Further, The Inventions of Groups I, II and VIII-IX represent separate and distinct antibody products because they bind to chemically distinct epitopes on a variety of distinct polypeptides that differ in amino acid sequence. Further, the search for antibodies that potentially bind to all of the different sequences, including the portions, and percentages of different amino acid segments would invoke a high search burden. Currently, there are approximately eight different databases that accompany the results of a search of one discrete amino acid or

nucleotide sequence and each result set from a particular database must be carefully considered. Hence, the search of four different polypeptides, and different polypeptide segments in the databases would require extensive searching and review. Furthermore, because these inventions are distinct for the reasons given above and the search required for one group is not required for another group, restriction for examination purposes as indicated is proper. Furthermore, the polynucleotide can be used for hybridization screening, the antibody can be used to immunopurify the polypeptide and the hybridoma product can be used to produce any antibody other than the claimed antibodies, for example. The examination of all groups would require different searches in the U.S. Patent shoes and the scientific literature and would require the consideration of different patentability issues. Thus the inventions I, II, III and VI-IX are patentably distinct.

The inventions of Groups IV and V are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success. In the instant case, Groups IV recites a method of diagnosing the presence or location of an HGF expressing tumor in a subject in need thereof, and Group V recites a method of treating cancer in a human, comprising the step of administering to said human an effective amount of said antibody. The method of diagnosing the presence or location of an HGF expressing tumor in a subject in need thereof differs from that of a method of treating cancer in a human. Thus, each group differs in method objectives, method steps and parameters and in the reagents used. Further, each group is unrelated as they comprise distinct

steps and utilize different products which demonstrates that each method has different mode of operation. Each invention further performs this function using structurally and functionally divergent material. Moreover, the methodology and materials necessary for detection differ significantly for each of the materials. The examination of all groups would require different searches in the U.S. PATENT shoes and the scientific literature and would require the consideration of different patentability issues. Thus Inventions IV and V are separate and distinct in having different method steps and different endpoints and are patentably distinct.

The inventions of Group I, II, VII-IX and the method of Groups IV and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (i) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see MPEP § 806.05(h)]. In the instant case the antibody product as claimed can be used in a materially different process such as affinity chromatography in addition to the materially different methods of Groups II-XXVI.

Election of species within Group I

3. This application contains claims directed to the following patentably distinct species of the claimed invention I

If group I is elected, the applicant is required to elect one species from the following list:

Species A) 11978

Species B) 11994

Species C) 12075

Species D) 12119

Species E) 12123

Species F) 12133

Species G) 12136

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-25 and 30 are generic.

The species discussed above patentably distinct because of their distinct properties including the differences in their sequences, the possible structure and function including the affinity and the antigen binding.

4. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims

are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Furthermore, because these inventions are distinct for the reasons given above and the search required for one group is not required for another group, restriction for examination purposes as indicated is proper.

6. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if

the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Parithosh K. Tungaturthi whose telephone number is 571-272-8789. The examiner can normally be reached on Monday through Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

9. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,
Parithosh K. Tungaturthi, Ph.D.
Ph: (571) 272-8789

LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER